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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,534	01/25/2002	Harry R. Davis	CV01378K	2339

24265 7590 10/16/2003

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/16/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/057,534

Applicant(s)

DAVIS ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 4,29,30,37-69,73,78 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-28,31-36,70-72,74-77,79 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 29, 30, 39, 41, 44, 46, 49, 51, 54, 59, 64, 66, 69, 73, 78, 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, claims 4, 37, 38, 40, 42-43, 45, 47-48, 50, 52-43, 55-58, 60-63, 65, 67-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.
2. Applicant's election with traverse of invention group I, claims 1-28, 31-38, 40, 42, 43, 45, 47, 48, 50, 52, 53, 55-58, 60-63, 65, 67, 68, 70-72, 74-77, 79 and 80, cholestyramine, ezetimibe, and simvastatin as the elected species in Paper No. 8 is acknowledged. The traversal is on the ground(s) that search and examination of claims 1-58 would not cause undue burden. This is not found persuasive because these inventions are distinct for the reasons given in prior office action and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected invention and species.

### *Claim Rejections 35 U.S.C. 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-3, 5-28, 31-36, 70-72, 74-77 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US 5,631,365, IDS) in view of Albright (US 5,300,288), Dechow (US 4,837,255), and Davis (US 5,661,145, IDS).

5. Rosenblum et al. teaches that hydroxy-substituted azetidinone compounds, including ezatemibe, are known to be useful for lowering cholesterol level. Rosenblum et al. further teaches that the hydroxy-substituted azetidinone compounds are particularly useful in combination with a cholesterol biosynthesis inhibitor. See, particularly, column 2, line 15 to column 3, line 66, example 6 in column 31-33.

6. Rosenblum et al. does not teach expressly a combination of a hydroxy-substituted azetidinone compounds, e.g., ezatemibe, and a bile acid sequestrant, e.g., cholestyramine, or further with a cholesterol biosynthesis inhibitor, e.g., simvastatin.

7. However, as shown in Albright, cholestyramine is an old and well-known cholesterol-lowering agent. See, column 2, lines 3-7. Dechow particularly, teaches a method of lowering cholesterol by administering to a patient a composition comprising cholestyramine. See, particularly, the claims. Davis teaches that simvastatin is a known cholesterol biosynthesis inhibitor, and is particularly useful with lactam cholesterol absorption inhibitor. See, particularly, column 2, lines 51-63.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make cholesterol lowering composition comprising the hydroxy-substituted azetidinone compound, ezatemibe, and the well-known cholesterol lowering agent, cholestyramine.

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A person of ordinary skill in the art would have been motivated to make cholesterol lowering composition comprising the hydroxy-substituted azetidinone compound, ezatemibe, and the well-known cholesterol lowering agent, cholestyramine. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known cholesterol lowering agent sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. The further employment of simvastatin in the combination is obvious because the hydroxy-substituted azetidinone compounds are known to be useful with cholesterol biosynthesis inhibitor. Further, the optimization of a result effective parameter, e.g., effective amount of a therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

Shengjun Wang

October 10, 2003